## IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE: DESLORATADINE PATENT LITIGATION

MDL No. 1851 Civil Action No. 3:07-cv-03930-MLC-TJB

SCHERING CORPORATION, Plaintiff,

ν.

ZYDUS PHARMACEUTICALS, USA, INC., SANDOZ INC., MYLAN PHARMACEUTICALS INC., ORGENUS PHARMA, INC., ORCHID CHEMICALS & PHARMACEUTICALS, LTD., L. PERRIGO CO., PERRIGO CO., GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS, LTD., GEOPHARMA, INC., BELCHER PHARMACEUTICALS, INC., LUPIN PHARMACEUTICALS INC., LUPIN LTD., RANBAXY INC., RANBAXY LABORATORIES LTD., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., CARACO PHARMACEUTICAL LABORATORIES. LTD., SUN PHARMACEUTICAL INDUSTRIES LTD., WATSON PHARMACEUTICALS, INC., and WATSON

Defendants.

LABORATORIES, INC.,

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AT 8:30\_\_\_\_\_WILLIAM T. WALSH M CLERK

Civil Action No. 06-04715-MLC-TJB

STIPULATION AND ORDER

The Court, upon the consent and request of Plaintiff Schering Corporation

("Schering") and Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively, "Lupin"),
hereby acknowledges the following Stipulation and issues the following Order.

## STIPULATION

- This Court has subject matter jurisdiction over this patent infringement action (the "Action") and personal jurisdiction over Schering and Lupin. Venue is proper in this Court as to Schering and Lupin.
- 2. In this Action, Schering has charged Lupin with infringement of United States Patent No. 6,100,274 ("the '274 Patent") in connection with Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 78-352 directed to generic tablets containing 5 milligrams of desloratedine per tablet to the U.S. Food and Drug Administration ("FDA").
- 3. In response to Schering's charges of patent infringement, Lupin Ltd. has alleged certain defenses, including that the '274 Patent is invalid and not infringed by the generic tablet product containing 5 milligrams of desloratedine per tablet that is the subject of ANDA No. 78-352. No decision has been obtained by either party from this Court regarding these charges of infringement or these defenses.
- 4. In response to Schering's charges of patent infringement, Lupin Pharmaceuticals, Inc. has moved the Court for an order pursuant to Fed. R. Civ. P. 12(b)(6) dismissing the Action against it for failure to state a claim upon which relief may be granted, and/or an order pursuant to Fed. R. Civ. P. 12(b)(1) dismissing the Action against it for lack of subject matter jurisdiction ("Motion to Dismiss").
- 5. Lupin has not rebutted the statutory presumption that the '274 Patent is valid and enforceable in this Action. This admission is without prejudice to Lupin's defenses that the '274 patent is invalid.

- 6. Lupin admits that the submission of ANDA No. 78-352 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic tablets containing 5 milligrams of desloratedine per tablet within the United States before the expiration of the '274 Patent was a technical act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Lupin's defenses that the '274 patent is invalid and/or that the product described by ANDA No. 78-352 does not infringe that patent.
- 7. Lupin has agreed that each of the defenses set forth in Defendant Lupin

  Ltd.'s Answer To Amended Complaint, including the allegations and averments contained
  therein, should be dismissed, without prejudice.
- 8. Lupin has further agreed that Lupin Pharmaceuticals, Inc.'s Motion to Dismiss should be denied, without prejudice.

## ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Schering and Lupin, IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:

- 1. The filing of ANDA No. 78-352 was a technical act of infringement of the '274 Patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding the presumptive validity of the '274 patent and/or whether the product described by ANDA No. 78-352 infringes that patent.
- 2. Lupin Ltd.'s defenses with respect to the '274 Patent are hereby dismissed, without prejudice.
- Lupin Pharmaceuticals, Inc.'s Motion to Dismiss is hereby denied, without prejudice.

- 4. Lupin, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet product containing 5 milligrams of desloratedine per tablet that is the subject of ANDA No. 78-352 during the life of the '274 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Schering, unless all of the claims of the '274 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.
- Schering and Lupin each expressly waives any right to appeal or otherwise move for relief from this Stipulation And Order.
- This Court retains jurisdiction over Schering and Lupin for purposes of enforcing this Stipulation And Order.
- 7. This Stipulation And Order shall finally resolve this Action between Schering and Lupin. Each party shall bear its own fees and costs in connection with this Action, including attorney fees.
- 8. The Clerk of the Court is directed to enter this Stipulation And Order forthwith.

SO ORDERED:

This /7 day of \_\_\_\_\_\_\_, 2008

HONORARLE MARY L. COOPER UNITED STATES DISTRICT JUDGE Order.

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